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DAVIDSON, DAVIDSON & KAPPEL, LLC 485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			AZPURU, CARLOS A	
			ART UNIT	PAPER NUMBER
			1615	

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Please find below and/or attached an Office communication concerning this application or proceeding.



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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Paper No. 20040123

Application Number: 10/047,060  
Filing Date: January 14, 2002  
Appellant(s): BAICHWAL ET AL.

**MAILED**

**FEB 20 2004**

**GROUP 2900**

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Leslye B. Davidson  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed 10/23/2004.

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**(1) *Real Party in Interest***

A statement identifying the real party in interest is contained in the brief.

**(2) *Related Appeals and Interferences***

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

**(3) *Status of Claims***

The statement of the status of the claims contained in the brief is correct.

**(4) *Status of Amendments After Final***

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

**(5) *Summary of Invention***

The summary of invention contained in the brief is correct.

**(6) *Issues***

The appellant's statement of the issues in the brief is correct.

**(7) *Grouping of Claims***

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because while claim 43 does use mean plus function language, it does so merely to substitute functional language for the actuator, chamber, and output port of claims 26-42. As such, all the claims should stand or fall together.

**(8) *Claims Appealed***

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(9) *Prior Art of Record***

5,239,993	Evans et al	9-1993
5,284,133	Burns et al	2-1994

**(10) *Grounds of Rejection***

The following ground(s) of rejection are applicable to the appealed claims:

Claims 26-43 are rejected under 35 U.S.C. 112, second paragraph. Claims 26 – 43 are also rejected under 35 USC 102(b) separately over Evans et al, and Burns et al. These rejections are set forth in prior Office Action, Paper No. 2/26/03. (Please note, the rejection under 35 USC 112, first paragraph was withdrawn in the advisory action of 08/14/2003.)

**(11) *Response to Argument***

In response to Appellant's summary, no allegation was made that these claims were "unclear", since this would indicate a first paragraph issue. Instead, this examiner has argued that neither the means plus function language of claim 43, nor the actuator, chamber or output port "particularly point out the invention" in a manner that is would render it definite as defined under 35 USC 112, second paragraph. Appellants attempt to define their device through composition limitations is similar to compositions with intended use language.

In response to appellants statements concerning the rejections under 35 USC 102(b), the composition limitations were considered, however they did not define over the prior art references which meet all the device limitations of the instant claims.

Appellant's statements as to the rejections and reasoning set forth in each is correct. However, while 35 USC 112, sixth paragraph does allow the omission of structure, material, or acts in support of performing the function given in the claims, the claim must also meet the requirements of 35 USC 112, second paragraph.

The argument here is not whether the use of means plus function language in claim 43 is proper. Indeed, no rejection was made under 35 USC 112, sixth paragraph. The question is whether applicant has adequately defined the invention in a manner in which those of ordinary skill would find it definite. In reciting the various prior art devices in support of appellant's arguments, it should also be noted that these references are specific as to the device limitations which define them over the prior art. For example, Priestly (215) and Struve ('403) has very detailed drawings and claim language which allow the ordinary practitioner to particularly point out the invention as required by 35 USC 112, second paragraph. Neither attempts to define their invention through the composition it is intended to dispense. Indeed, applicant appears to recognize this by quoting Struve in that the type of composition used is "not important to the invention". This statement would appear to support this examiner's arguments.

The same argument applies to claims 26-42, which include device limitations of an actuator, a chamber , and an output port. This examiner is not arguing that applicant does not intend to claim a device, but review of the claims limitations would not allow the ordinary practitioner to particularly point out the invention as set out in 35 USC 112, second paragraph. Appellants are arguing that the presence of the pharmaceutical formulation is enough to distinguish over the prior art devices. But it must also be questioned whether the empty device would adequately define over the prior art? The answer is no, and the use of the pharmaceutical within the device can not make the device claims definite.

In referring to the prior art rejections, appellant's arguments restating the rejections are correct. It is also agreed that each and every limitation must be met as a requirement for a proper rejection under 35 USC 102(b). Both Evans et al, and Burns et al comprise an actuator, chamber, and an output port, which can be generally construed as a means of delivering. Since appellants are claiming a device , not a pharmaceutical, all the device limitations have been met.

Further if appellant had claimed an improved (device) element, the claims would have been novel over the prior art. The case law cited by Appellants was rebutted in the final rejection of 02/26/2003. However, it should be noted that in each case, the courts were referring to limitations of the claimed invention , and not those of an unclaimed invention within the device. The pharmaceutical limitations are not being ignored as referred to in the Supreme Court decision *Diamond v Diehr*, 450 US 181 (1981),

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however as written the device claimed does not include any improvements of the device itself. Clearly, the references to Evans et al, and Burns et al meet all the device limitations found in the instant claims. The distinction between what is being claimed (a device) and the pharmaceutical within it is not irrelevant.

The rejections cited herein were not cited to show that pharmaceuticals can not be stored within devices. Clearly, that would be an improper statement. However, when those of ordinary skill read the instant claims, they would have found that the device limitations found therein would have been anticipated by those same features as set out by Evans et al and Burns et al, respectively.

In conclusion, it is not agreed that the device claims as set out meet the requirements of 35 USC 112, second paragraph, and are therefore indefinite. Further, it is believed the prior art references to Evans et al and Burns et al anticipate the claimed device.

For the above reasons, it is believed that the rejections should be sustained.

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Respectfully submitted,

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February 12, 2004

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